

take into account the results of an updated health risk assessment, as those terms are defined in this section:

(i) Review (and administration, if needed) of an updated health risk assessment (as defined in this section).

(ii) An update of the individual's medical and family history.

(iii) An update of the list of current providers and suppliers that are regularly involved in providing medical care to the individual as that list was developed for the first annual wellness visit providing personalized prevention plan services or the previous subsequent annual wellness visit providing personalized prevention plan services.

(iv) Measurement of an individual's weight (or waist circumference), blood pressure and other routine measurements as deemed appropriate, based on the individual's medical and family history.

(v) Detection of any cognitive impairment that the individual may have, as that term is defined in this section.

(vi) An update to the following:

(A) The written screening schedule for the individual as that schedule is defined in paragraph (a) of this section for the first annual wellness visit providing personalized prevention plan services.

(B) The list of risk factors and conditions for which primary, secondary or tertiary interventions are recommended or are underway for the individual as that list was developed at the first annual wellness visit providing personalized prevention plan services or the previous subsequent annual wellness visit providing personalized prevention plan services.

(vii) Furnishing of personalized health advice to the individual and a referral, as appropriate, to health education or preventive counseling services or programs as that advice and related services are defined in paragraph (a) of this section.

(viii) Any other element determined appropriate through the national coverage determination process.

(b) *Conditions for coverage of annual wellness visits providing personalized prevention plan services.* Medicare Part B pays for first and subsequent annual wellness visits providing personalized prevention plan services that are fur-

nished to an eligible beneficiary, as described in this section, if they are furnished by a health professional, as defined in this section.

(c) *Limitations on coverage of an annual wellness visit providing personalized prevention plan services.* Payment may not be made for either a first or a subsequent annual wellness visit providing personalized prevention plan services that is performed for an individual who is—

(1) Not an eligible beneficiary as described in this section.

(2) An eligible beneficiary as described in this section and who has had either an initial preventive physical examination as specified in § 410.16 of this subpart or either a first or a subsequent annual wellness visit providing personalized prevention plan services performed within the past 12 months.

(d) *Effective date.* Coverage for an annual wellness visit providing personalized prevention plan services is effective for services furnished on or after January 1, 2011.

[75 FR 73613, Nov. 29, 2010, as amended at 76 FR 1367, Jan. 10, 2011; 76 FR 73470, Nov. 28, 2011]

**§ 410.16 Initial preventive physical examination: Conditions for and limitations on coverage.**

(a) *Definitions.* As used in this section, the following definitions apply:

*Eligible beneficiary* means, for the purposes of this section, an individual who receives his or her initial preventive examination not more than 1 year after the effective date of his or her first Medicare Part B coverage period.

*End-of-life planning* means, for purposes of this section, verbal or written information regarding the following areas:

(1) An individual's ability to prepare an advance directive in the case where an injury or illness causes the individual to be unable to make health care decisions.

(2) Whether or not the physician is willing to follow the individual's wishes as expressed in an advance directive.

*Initial preventive physical examination* means all of the following services furnished to an eligible beneficiary by a physician or other qualified nonphysician practitioner with the goal of

health promotion and disease detection:

(1) Review of the beneficiary's medical and social history with attention to modifiable risk factors for disease, as those terms are defined in this section.

(2) Review of the beneficiary's potential (risk factors) for depression, including current or past experiences with depression or other mood disorders, based on the use of an appropriate screening instrument for persons without a current diagnosis of depression, which the physician or other qualified nonphysician practitioner may select from various available standardized screening tests designed for this purpose and recognized by national professional medical organizations.

(3) Review of the beneficiary's functional ability, and level of safety as those terms are defined in this section, as described in paragraph (4) of this definition, based on the use of appropriate screening questions or a screening questionnaire, which the physician or other qualified nonphysician practitioner may select from various available screening questions or standardized questionnaires designed for this purpose and recognized by national professional medical organizations.

(4) An examination to include measurement of the beneficiary's height, weight, body mass index, blood pressure, a visual acuity screen, and other factors as deemed appropriate, based on the beneficiary's medical and social history, and current clinical standards.

(5) End-of-life planning as that term is defined in this section upon agreement with the individual.

(6) Education, counseling, and referral, as deemed appropriate by the physician or qualified nonphysician practitioner, based on the results of the review and evaluation services described in this section.

(7) Education, counseling, and referral, including a brief written plan such as a checklist provided to the individual for obtaining an electrocardiogram, as appropriate, and the appropriate screening and other preventive services that are covered as separate Medicare Part B benefits as described in sections 1861(s)(10), (jj), (nn), (oo),

(pp), (qq)(1), (rr), (uu), (vv), (xx)(1), (yy), (bbb), and (ddd) of the Act.

*Medical history* is defined to include, at a minimum, the following:

(1) Past medical and surgical history, including experiences with illnesses, hospital stays, operations, allergies, injuries, and treatments.

(2) Current medications and supplements, including calcium and vitamins.

(3) Family history, including a review of medical events in the beneficiary's family, including diseases that may be hereditary or place the individual at risk.

A *physician* for purposes of this section means a doctor of medicine or osteopathy (as defined in section 1861(r)(1) of the Act).

A *qualified nonphysician practitioner* for purposes of this section means a physician assistant, nurse practitioner, or clinical nurse specialist (as authorized under section 1861(s)(2)(K)(i) and section 1861(s)(2)(K)(ii) of the Act and defined in section 1861(aa)(5) of the Act, or in §§ 410.74, 410.75, and 410.76).

*Review of the beneficiary's functional ability and level of safety* must include, at a minimum, a review of the following areas:

(1) Hearing impairment.

(2) Activities of daily living.

(3) Falls risk.

(4) Home safety

*Social history* is defined to include, at a minimum, the following:

(1) History of alcohol, tobacco, and illicit drug use.

(2) Diet.

(3) Physical activities.

(b) *Condition for coverage of an initial preventive physical examination.* Medicare Part B pays for an initial preventive physical examination provided to an eligible beneficiary, as described in this section, if it is furnished by a physician or other qualified nonphysician practitioner, as defined in this section.

(c) *Limitations on coverage of initial preventive physical examinations.* Payment may not be made for an initial

preventive physical preventive examination that is performed for an individual who is not an eligible beneficiary as described in this section.

[69 FR 66420, Nov. 15, 2004, as amended at 71 FR 69783, Dec. 1, 2006; 73 FR 69932, Nov. 19, 2008]

#### § 410.17 Cardiovascular disease screening tests.

(a) *Definition.* For purposes of this subpart, the following definition apply:

*Cardiovascular screening blood test* means:

(1) A lipid panel consisting of a total cholesterol, HDL cholesterol, and triglyceride. The test is performed after a 12-hour fasting period.

(2) Other blood tests, previously recommended by the U.S. Preventive Services Task Force (USPSTF), as determined by the Secretary through a national coverage determination process.

(3) Other non-invasive tests, for indications that have a blood test recommended by the USPSTF, as determined by the Secretary through a national coverage determination process.

(b) *General conditions of coverage.* Medicare Part B covers cardiovascular disease screening tests when ordered by the physician who is treating the beneficiary (see § 410.32(a)) for the purpose of early detection of cardiovascular disease in individuals without apparent signs or symptoms of cardiovascular disease.

(c) *Limitation on coverage of cardiovascular screening tests.* Payment may be made for cardiovascular screening tests performed for an asymptomatic individual only if the individual has not had the screening tests paid for by Medicare during the preceding 59 months following the month in which the last cardiovascular screening tests were performed.

[69 FR 66421, Nov. 15, 2004]

#### § 410.18 Diabetes screening tests.

(a) *Definitions.* For purposes of this section, the following definitions apply:

*Diabetes* means diabetes mellitus, a condition of abnormal glucose metabolism diagnosed using the following criteria: a fasting blood sugar greater

than or equal to 126 mg/dL on two different occasions; a 2-hour post-glucose challenge greater than or equal to 200 mg/dL on two different occasions; or a random glucose test over 200 mg/dL for a person with symptoms of uncontrolled diabetes.

*Pre-diabetes* means a condition of abnormal glucose metabolism diagnosed using the following criteria: a fasting glucose level of 100–125 mg/dL, or a 2-hour post-glucose challenge of 140–199 mg/dL. The term pre-diabetes includes the following conditions:

(1) Impaired fasting glucose.

(2) Impaired glucose tolerance.

(b) *General conditions of coverage.* Medicare Part B covers diabetes screening tests after a referral from a physician or qualified nonphysician practitioner to an individual at risk for diabetes for the purpose of early detection of diabetes.

(c) *Types of tests covered.* The following tests are covered if all other conditions of this subpart are met:

(1) Fasting blood glucose test.

(2) Post-glucose challenges including, but not limited to, an oral glucose tolerance test with a glucose challenge of 75 grams of glucose for non-pregnant adults, a 2-hour post glucose challenge test alone.

(3) Other tests as determined by the Secretary through a national coverage determination.

(d) *Amount of testing covered.* Medicare covers the following for individuals:

(1) Diagnosed with pre-diabetes, two screening tests per calendar year.

(2) Previously tested who were not diagnosed with pre-diabetes, or who were never tested before, one screening test per year.

(e) *Eligible risk factors.* Individuals with the following risk factors are eligible to receive the benefit:

(1) Hypertension.

(2) Dyslipidemia.

(3) Obesity, defined as a body mass index greater than or equal to 30 kg/m<sup>2</sup>.

(4) Prior identification of impaired fasting glucose or glucose intolerance.

(5) Any two of the following characteristics:

(i) Overweight, defined as body mass index greater than 25, but less than 30 kg/m<sup>2</sup>.